TESS Hydrocarbon Ingestion and Aspirations

Method

The American Association of Poison Control Centers' Toxic Exposure Surveillance System compiles data on reported poisoning incidents in the United States [6]. TESS data are based on follow-up investigations of telephone calls reporting poisoning exposures to poison control centers. All certified poison control centers in the U.S. participate in TESS, but the number of participating centers fluctuates annually. Since TESS is not a probability sample of poison control centers, TESS data do not provide national estimates. However, TESS data are the most comprehensive data available on pediatric toxic exposures in the U.S. CPSC purchases TESS data for victims under 5 years old annually.

This report presents TESS data on *general unintentional ingestion and aspiration exposures* involving children under 5 years old. General unintentional exposures are defined in TESS as unintentional exposures that do not involve environmental or occupational exposure, therapeutic error, misuse of the product, bite/sting, food poisoning, or an unknown source of exposure. Aspirations are defined in TESS as exposures by the pulmonary (tracheal) route that are usually associated with the ingestion of liquid or solid agents. TESS automatically codes all aspiration exposures as ingestion exposures. TESS generic codes capture related groups of substances involved in toxic exposures.

This report presents data for 2 classes of substances, referred to in the present report as *cosmetics and household chemicals*, that frequently contain hydrocarbon compounds known to pose an aspiration hazard to young children. The *cosmetics* class includes the groups (generic codes): creams/lotions/makeup (077322), nail products/miscellaneous (077325), bath oil/bubble bath (077329), suntan/sunscreen products (077345). The *household chemicals* class includes the groups (TESS generic codes): carpet/upholstery/leather/vinyl cleaner (013290), automotive hydrocarbons (039220), spot remover/dry cleaning - hydrocarbon (039281), lubricating oil/motor oil (039505), hydrocarbon - other (039510), hydrocarbon - unknown (039511), rust remover/other/unknown (077307), floor wax/polish/sealer (077586), toluene/xylene - adhesive only (191103), toluene/xylene - excluding adhesive (191500), stains (254366), varnish/lacquers (254367). In the following, data are presented first for cosmetics, then for household chemicals, and finally for cosmetics and household chemicals combined.

Cosmetics

Ingestions

Table 2 gives cosmetic *ingestions* for children under 5 years old by age and year. There were 74,042 ingestions from 1995 through 1997. Age was unspecified for 126 cases. Of the 73,916 cases of specified age, the largest percentage involved children 12-23 months old (46.1%), with 2-year olds next (29.1%), and 0-11-month olds third (14.4%).

Table 2. *Cosmetic Ingestions Reported to TESS for Children under 5 Years Old by Age and Year*

Age	1995	1996	1997	Total
0-11 Months	3,112	3,633	3,936	10,681
12-23 Months	9,937	11,680	12,425	34,042
2 Years	6,465	7,472	7,563	21,500
3 Years	1,683	1,987	2,083	5,753
4 Years	627	697	616	1,940
Unknown	26	45	55	126
Total	21,850	25,514	26,678	74,042

Source: American Association of Poison Control Centers' TESS file.

Aspirations: Age

Table 3 gives cosmetic aspirations reported to TESS for children under 5 years old by age and year. There were 114 reported aspirations from 1995 through 1997. Age was unspecified for 1 case. Of the 113 cases of specified age, the largest percentage involved children 12-23 months old (54%), with 2-year olds next (21%), and 0-11-month olds third (12%).

Table 3. *Cosmetic Aspirations Reported to TESS for Children under 5 Years Old by Age and Year*

Age	1995	1996	1997	Total
0-11 Months	1	2	11	14
12-23 Months	19	22	20	61
2 Years	6	5	13	24
3 Years	2	3	3	8
4 Years	1	3	2	6
Unknown	0	1	0	1
Total	29	36	49	114

Source: American Association of Poison Control Centers' TESS file.

Aspirations: Medical Outcome

Table 4 gives cosmetic aspirations reported to TESS for children under 5 years old by medical outcome [7]. Of 114 aspiration cases, 5 resulted in a moderate medical outcome, 2 resulted in a major medical outcome, and 1 resulted in death. There was no follow up information for 51 cases, because they were minor or the family could not be reached.

Table 4. *Cosmetic Aspirations Reported to TESS for Children under 5 Years Old by Medical Outcome for 1995 through 1997*

Medical Outcome	Total
None	13
Minor	41
Moderate	5
Major	2
Death	1
Unrelated effect	1
No follow up	51
Total	114

Source: American Association of Poison Control Centers' TESS file.

Aspirations: Respiratory Effects

Table 5 gives the number of cosmetic aspiration cases reported to TESS for children under 5 years old with related respiratory effects [8]. Coughing/choking was the most frequently reported respiratory effect. In addition, there were 2 cases of pneumonitis, 1 of respiratory arrest, 2 of respiratory depression, and 3 of positive X-Ray findings.

Table 5. *Cosmetic Aspirations Reported to TESS for Children under 5 Years Old by Respiratory Effect for 1995 through 1997*

Respiratory Effect	Number
Bronchospasm	3
Cough/Choke	38
Cyanosis	0
Dyspnea	4
Hyperventilation/Tachypnea	2
Pneumonitis	2
Pulmonary Edema	0
Respiratory Arrest	1
Respiratory Depression	2
Positive X-Ray Findings	3

Source: American Association of Poison Control Centers' TESS file.

Household Chemicals

Ingestions

Table 6 gives household chemical *ingestions* reported to TESS for children under 5 years old by age and year. There were 44,781 ingestions from 1995 through 1997. Age was unspecified for 10 cases. Of the 44,771 cases of specified age, the largest percentage involved children 12-23 months old (43.3%), with 2-year olds next (33.9%), and 3-year olds third (10.8%).

Table 6. *Household Chemical Ingestions Reported to TESS for Children under 5 Years Old by Age and Year*

Age	1995	1996	1997	Total
0-11 Months	1,048	1,229	1,241	3,518
12-23 Months	5,505	7,134	6,741	19,380
2 Years	4,295	5,587	5,281	15,163
3 Years	1,250	1,789	1,778	4,817
4 Years	492	693	708	1,893
Unknown	2	1	7	10
Total	12,592	16,433	15,756	44,781

Source: American Association of Poison Control Centers' TESS file.

Aspirations: Age

Table 7 gives household chemical *aspirations* reported to TESS for children under 5 years old by age and year. There were 612 reported aspirations from 1995 through 1997. Age was specified for all cases. The largest percentage of cases involved children 12-23 months old (48.4%), with 2-year olds next (34.6%), and 3-year olds third (9.6%).

Table 7. *Household Chemical Aspirations Reported to TESS for Children under 5 Years Old by Age and Year*

Age	1995	1996	1997	Total
0-11 Months	2	7	10	19
12-23 Months	46	149	101	296
2 Years	39	85	88	212
3 Years	9	27	23	59
4 Years	1	14	11	26
Total	97	282	233	612

Source: American Association of Poison Control Centers' TESS file.

Aspirations: Medical Outcome

Table 8 gives household chemical aspirations reported to TESS for children under 5 years old by medical outcome [7]. Of the 612 cases from 1995 through 1997, 122 (19.9%) resulted in a moderate medical outcome, and 4 (0.7%) resulted in a major medical outcome.

Table 8. *Household Chemical Aspirations Reported to TESS for Children under 5 Years Old by Medical Outcome for 1995 through 1997*

Medical Outcome	Total
None	66
Minor	286
Moderate	122
Major	4
Death	0
Unrelated effect	8
No follow up	126
Total	612

Source: American Association of Poison Control Centers' TESS file.

Aspirations: Respiratory Effects

Table 9 gives the number of household chemical aspiration cases reported to TESS for children under 5 years old with related respiratory effects [8]. Coughing/choking was the most frequent respiratory effect. In addition, there were 31 cases of pneumonitis, 1 of pulmonary edema, 5 of respiratory depression, and 73 of positive X-Ray findings.

Table 9. *Household Chemical Aspirations Reported to TESS for Children under 5 Years Old by Respiratory Effect for 1995 through 1997*

Respiratory Effect	Number Related
Bronchospasm	12
Cough/Choke	370
Cyanosis	4
Dyspnea	48
Hyperventilation/Tachypnea	32
Pneumonitis	31
Pulmonary Edema	1
Respiratory Arrest	0
Respiratory Depression	5
Positive X-Ray Findings	73

Source: American Association of Poison Control Centers' TESS file.

Cosmetics and Household Chemicals Combined

Ingestions and Aspirations

Table 10 gives *ingestions* and *aspirations* in the combined household chemicals and cosmetics groups reported to TESS for children under 5 years old by year.

Table 10. *Cosmetic and Household Chemical Ingestions and Aspirations Reported to TESS for Children under 5 Years old by Year*

	1995	1996	1997	Total
Ingestions	34,442	41,947	42,434	118,823
Aspirations	126	318	282	726

Source: American Association of Poison Control Centers' TESS file.

Aspirations: Medical Outcome

Table 11 gives *combined cosmetic and household chemical aspirations* reported to TESS for children under 5 years old by medical outcome [7]. Of the 726 cases from 1995 through 1997, 127 (17.5%) resulted in a moderate medical outcome, 6 (0.8%) resulted in a major medical outcome, and 1 (0.1%) resulted in a fatality.

Table 11. *Cosmetic and Household Chemical Aspirations Reported to TESS for Children under 5 Years Old by Medical Outcome and Year*

Medical Outcome	1995	1996	1997	Total
None	8	29	42	79
Minor	64	142	121	327
Moderate	21	61	45	127
Major	1	2	3	6
Death	0	1	0	1
Unrelated effect	2	6	1	9
No follow up	30	77	70	177
Total	126	318	233	726

Source: American Association of Poison Control Centers' TESS file.

Aspirations: Respiratory Effects

Table 12 gives the number of household chemical aspiration cases reported to TESS for children under 5 years old with related respiratory effects [8]. Coughing/choking was the most frequent respiratory effect. In addition, there were 33 cases of pneumonitis, 1 of pulmonary edema, 1 of respiratory arrest, 7 of respiratory depression, and 76 of positive X-Ray findings.

Table 12. *Total Cosmetic and Household Chemical Aspirations Reported to TESS for Children under 5 Years Old by Respiratory Effect*

Respiratory Effect	Number Related
Bronchospasm	15
Cough/Choke	408
Cyanosis	4
Dyspnea	52
Hyperventilation/Tachypnea	34
Pneumonitis	33
Pulmonary Edema	1
Respiratory Arrest	1
Respiratory Depression	7
Positive X-Ray Findings	76

Source: American Association of Poison Control Centers' TESS file.

Conclusion

This report documents a high incidence of pediatric exposure to cosmetics and household chemical product groups that frequently contain hydrocarbon compounds known to pose an aspiration hazard to young children. Data sources include the U.S. Consumer Product Safety Commission's National Electronic Injury Surveillance System (NEISS) and the American Association of Poison Control Centers' Toxic Exposure Surveillance System (TESS).

NEISS data for 1995 through 1997 yielded an estimated total number of pediatric ingestions involving household chemicals of about 6,800 ± 1,800. NEISS household chemical data are not directly comparable to TESS data, because NEISS product code categories do not correspond to TESS generic code categories. NEISS does not currently distinguish different cosmetic products, so cosmetic-related injuries reported to NEISS are not included in this report.

From 1995 through 1997, there were 118,823 pediatric ingestion exposures reported in TESS, with 74,042 related to cosmetics, and 44,781 related to household chemicals. During the same period, there were 726 reported aspiration exposures, with 114 related to cosmetics, and 612 related to household chemicals.

TESS data indicated that children 12 to 36 months old are most likely to be involved in pediatric hydrocarbon ingestion and aspiration exposure incidents, with children 12 to 23 months old more frequently involved than children 24 to 36 months old. Children 12 to 23 months old were involved in 46.1% of *cosmetic ingestions*, 43.3% of *household chemical ingestions*, 53.5% of *cosmetic aspirations*, and 48.4% of *household chemical aspirations*. Children 24 to 36 months old were involved in 29.1% of *cosmetic ingestions*, 33.9% of *household chemical ingestions*, 21.1% of *cosmetic aspirations*, and 34.6% of *household chemical aspirations*.

TESS data indicated the potential for severe medical consequences following pediatric hydrocarbon aspiration exposure. Of the 726 aspirations in the cosmetics and household chemicals groups, 127 resulted in a moderate medical outcome, 6 resulted in a major medical outcome, and 1 resulted in a fatality. Specific respiratory effects resulting from aspiration of these cosmetics or household chemicals groups were documented including 76 positive X-ray findings, 33 cases of pneumonitis, 1 case of pulmonary edema, 7 cases of respiratory depression, and 1 case of respiratory arrest.

Notes

1. Boudreault MA, Singh H. *Petroleum Distillates and Pine Oil Products*. Washington, DC: U.S. Consumer Product Safety Commission; 1997.

2. Kessler E, Reiff L, Schroeder T. *The NEISS Sample: Design and Implementation.* Washington, DC: US Consumer Product Safety Commission; 1997.

3. McDonald AK. *The National Electronic Injury Surveillance System: A Tool for Researchers*. Washington, DC: U.S. Consumer Product Safety Commission; 1994.

4. Marker D, Lo A, Brick M, Davis W. *Comparisons of National Estimates from Different Samples and Different Sampling Frames of the National Electronic Injury Surveillance System (NEISS)*. Report prepared for the U.S. Consumer Product Safety Commission. Rockville, MD. Westat; 25 Jan 1999.

5. Kessler E, Schroeder T. *National Electronic Injury Surveillance System (NEISS) Estimated Generalized Relative Sampling Errors*. Washington, DC: US Consumer Product Safety Commission; Oct 1998.

6. Litovitz TL, Smilkstein M, Felberg L, Klein-Schwartz W, Berlin R, Morgan JL. 1996 Annual Report of the American Association of Poison Control Centers Toxic Exposure Surveillance System. *Am J Emerg Med*. 1997;15:447-500.

7. **Definitions of Medical Outcomes in TESS**

   No Effect: The patient developed no signs or symptoms as a result of the exposure.

   Minor Effect: The patient developed some signs or symptoms as a result of the exposure, but they were minimally bothersome and generally resolved rapidly without residual disability or disfigurement.

   Moderate Effect: The patient exhibited signs or symptoms as a result of the exposure that were more pronounced, more prolonged, or more of a systemic nature than minor symptoms. Symptoms were not life-threatening, and the patient has no residual disability. Usually some form of treatment is indicated.

   Major Effect: The patient exhibited signs or symptoms as a result of the exposure that were life-threatening or resulted in significant residual disability or disfigurement, e.g., repeated seizures or status epilepticus, respiratory compromise requiring intubation, ventricular tachycardia with hypotension.

   Death: Only those deaths which are probably or undoubtedly related to the exposure are coded here.

   Unrelated Effect: The exposure was probably not responsible for the clinical effect.

No Follow Up: Either the patient could not be followed in spite of a potentially significant exposure or follow-up calls were limited because the substance implicated was nontoxic, the amount was insignificant, or the exposure was likely to result in only minimal toxicity.

8. **Definitions of Respiratory Effects in TESS**

Bronchospasm: Narrowing of bronchi by muscular contraction in response to some stimulus; wheezing; reactive airway diseases.

Cough/Choke: A form of violent exhalation by which irritant particles in the airways can be expelled; interruption of respiration by obstruction.

Cyanosis: Bluish discoloration of the skin and mucuous membranes.

Dyspnea: Labored or difficult breathing; shortness of breath.

Hyperventilation/Tachypnea: Breathing at an abnormally rapid rate at rest; diagnosis is usually made with an arterial blood gas.

Pneumonitis: Inflammation of the pulmonary parenchyma.

Pulmonary edema: Accumulation of fluid in the lungs. Include cardiogenic and noncardiogenic etiologies.

Respiratory arrest: Cessation of spontaneous respirations.

Respiratory depression: Diminshed tidal volume and/or rate. Inadequate ventilation. Use this code only if objective information is provided to support the diagnosis of respiratory depression.

X-ray findings (+): Pulmonary x-ray findings other than normal.

TAB D

United States
CONSUMER PRODUCT SAFETY COMMISSION
Washington, D.C. 20207

MEMORANDUM

DATE: OCT 30 1998

TO: Suzanne Barone, Ph.D., Pharmacologist, EHHS

Through: Mary Ann Danello, Ph.D., Associate Executive Director MAD for SBD
Directorate for Epidemiology and Health Sciences

Susan Ahmed, Ph.D., Director, Division of Hazard Analysis SA

FROM: C. Craig Morris, Ph.D., EHHA CCM

SUBJECT: Pediatric Baby Oil Exposure Incidents

Per your request, please find attached a brief report on pediatric baby oil exposure incidents summarizing 1996 and 1997 Toxic Exposure Surveillance System (TESS) data from the American Association of Poison Control Centers (AAPCC).

Pediatric Baby Oil Exposures Reported to the AAPCC

AAPCC Toxic Exposure Surveillance System

This report summarizes pediatric baby oil exposure data for calendar years 1996 and 1997 from the Toxic Exposure Surveillance System (TESS) of the American Association of Poison Control Centers (AAPCC). TESS compiles data on reported poisoning incidents in the United States. TESS data derive from follow-up investigations of telephone calls reporting poisoning exposures to poison control centers. TESS is not a probability sample of poison control centers in the U.S., and the number of participating centers varies from year to year, but all certified poison control centers in the U.S. participate in the system. TESS data cannot provide national estimates, but do provide useful information and minimal counts of reported product-related poisonings. Following are TESS data for baby oil exposures involving victims under 5 years old during 1996 and 1997. The data are from a special TESS data set purchased by the U.S. Consumer Product Safety Commission (CPSC) from AAPCC on 16 Sep 1998.

Pediatric Baby Oil Exposures by Gender

Table 1 gives general unintentional baby oil exposures by gender for children under 5 years old. General unintentional exposures are defined in TESS as those unintentional exposures that do not involve environmental or occupational exposure, therapeutic error, misuse of the product, bite/sting, food poisoning, or an unknown source of exposure. There were 1,139 general unintentional exposures in 1996 and 1,421 in 1997. As is generally the case with unintentional pediatric poisonings (Note 1), males were more frequent victims than females in both 1996 (58% versus 42%, $Z = 5.72$, $p < .01$, 2-tailed) and 1997 (53% versus 46%, $Z = 2.63$, $p < .01$, 2-tailed).

Table 1. *Baby Oil-Related Exposures Reported to TESS by Gender for Children under 5 Years Old*

Year	Total	Male (%)	Female (%)	Unknown (%)
1996	1,139	666 (58)	473 (42)	0 (0)
1997	1,421	759 (53)	660 (46)	2 (0)
Total	2,560	1,425 (56)	1,133 (44)	2 (0)

Source: American Association of Poison Control Centers TESS file.
Note: Percentages of total in parentheses may not sum to 100 due to rounding.

Pediatric Baby Oil Exposures by Medical Outcome

Table 2 gives general unintentional baby oil exposures by medical outcome for children under 5 years old. The TESS medical outcome categories are defined in Note 2.

Table 2. *Baby Oil-Related Exposures Reported to TESS by Medical Outcome for Children under 5 Years Old*

Medical Outcome	Total	1996	1997
None	705	322	383
Minor	164	76	88
Moderate	9	6	3
Major	1	0	1
Death	1	1	0
Unrelated effect	45	19	26
No follow up	1,635	715	920
Total	2,560	1,139	1,421

Source: American Association of Poison Control Centers TESS file.

Pediatric Baby Oil Exposures by Exposure Site

Table 3 gives baby oil exposures by exposure site for children under 5 years old. These data combine *all* TESS categories of reported pediatric baby oil exposures, including intentional, unintentional, other, adverse reaction, unknown, missing, and invalid.

Table 3. *Baby Oil-Related Exposures Reported to TESS by Exposure Site for Children under 5 Years Old*

Exposure Site	Total	1996	1997
Own Residence	2,519	1,122	1,397
Other Residence	51	23	28
Health Care Facility	1	1	0
School	2	1	1
Public Area	3	0	3
Other	1	1	0
Unknown	2	1	1
Total	2,579	1,149	1,430

Source: American Association of Poison Control Centers TESS file.

Pediatric Baby Oil Exposures by Management Site

Table 4 gives baby oil exposures by management site for children under 5 years old. These data combine *all* TESS categories of reported pediatric baby oil exposures, including intentional, unintentional, other, adverse reaction, unknown, missing, and invalid.

Table 4. *Baby Oil-Related Exposures Reported to TESS by Management Site for Children under 5 Years Old*

Management Site	Total	1996	1997
Managed on Site/Non-Health Care Facility	2,491	1,108	1,383
Managed in Health Care Facility			
Treated/Released	60	26	34
Admitted to Critical Care	1	1	0
Admitted to Noncritical Care	3	2	1
Admitted to Psychiatry	0	0	0
Lost Follow Up/Left AMA	17	6	11
Other	1	1	0
Refused Referral	2	2	0
Unknown	4	3	1
Total	2,579	1,149	1,430

Source: American Association of Poison Control Centers TESS file.

Notes

1. Schacter L. *Unintentional ingestions of medications by children under 5 years of age (January - March 1989).* Washington, DC: US Consumer Product Safety Commission; 1990.

2. Definitions of medical outcomes in TESS.

No Effect: The patient developed no signs or symptoms as a result of the exposure.

Minor Effect: The patient developed some signs or symptoms as a result of the exposure, but they were minimally bothersome and generally resolved rapidly without residual disability or disfigurement.

Moderate Effect: The patient exhibited signs or symptoms as a result of the exposure that were more pronounced, more prolonged, or more of a systemic nature than minor symptoms. Symptoms were not life-threatening, and the patient has no residual disability. Usually some form of treatment is indicated.

Major Effect: The patient exhibited signs or symptoms as a result of the exposure that were life-threatening or resulted in significant residual disability or disfigurement, e.g., repeated seizures or status epilepticus, respiratory compromise requiring intubation, ventricular tachycardia with hypotension.

Death: Only those deaths which are probably or undoubtedly related to the exposure are coded here.

Unrelated Effect: The exposure was probably not responsible for the clinical effect.

No Follow Up: Either the patient could not be followed in spite of a potentially significant exposure or follow-up calls were limited because the substance implicated was nontoxic, the amount was insignificant, or the exposure was likely to result in only minimal toxicity.

TAB E

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, D.C. 20207

MEMORANDUM

DATE: February 16, 1999

To: Suzanne Barone, Ph.D., Project Manager, Hydrocarbon Containing Products, Division of Health Sciences

Through: Mary Ann Danello, Ph.D., Associate Executive Director for Epidemiology and Health Sciences

Lori E. Saltzman, M.S., Director, Division of Health Sciences, Directorate for Epidemiology and Health Sciences

From: Tewabe Asebe, MSME, MSCE, Industrial Engineer, CPP, Division of Health Sciences T. A.

SUBJECT: Technical Feasibility, Practicability, and Appropriateness assessment of Child-Resistant (CR) Packaging for products containing 10% hydrocarbons or more by weight and a viscosity of less than 100 saybolt universal seconds (SUS) at 100 °F

The attached evaluation summarizes the Division of Health Sciences' assessment of technical feasibility, practicability, and appropriateness for senior friendly CR packaging for products containing 10% hydrocarbons or more by weight and a viscosity of less than 100 SUS at 100 °F.

BACKGROUND

The U.S. Consumer Product Safety Commission (CPSC or Commission) can issue requirements that certain household substances be sold in "special packaging" or child-resistant (CR) packaging under the Poison Prevention Packaging Act (PPPA or the Act) of 1970. To require CR packaging for products containing 10% hydrocarbons or more by weight and a viscosity of less than 100 SUS at 100 °F, the Commission needs to make the finding that CR packaging is technically feasible, practicable, and appropriate for these products (15 U.S.C. 1472 (a)(2) Sec. 3).

Technical feasibility exists when technology is available or can be readily developed to produce packaging that conforms to the standards.

Practicability means that special packaging complying with the standards is adaptable to modern mass production and assembly line techniques.

Packaging is appropriate when it will adequately protect the integrity of the substance and not interfere with its intended storage or use.

Existing Regulations for Petroleum Distillates Products

Prepackaged liquid kindling and/or illuminating preparations, such as cigarette lighter fuel, charcoal lighter fuel, camping equipment fuel, torch fuel, and fuel for decorative or functional lanterns, furniture polish products, and solvents for paint or other similar surface-coating material containing 10% or more by weight of petroleum distillates and having a viscosity of less than 100 SUS at 100 °F are already required to be packaged in CR packaging under the PPPA[28,29].

TECHNICAL FEASIBILITY

Thirty example representatives of hydrocarbon containing products were evaluated by the staff. From these, sixteen products were determined, by the CPSC Laboratory of Sciences, Division of Chemistry (LSC), to contain 10% hydrocarbons or more by weight and a viscosity of less than 100 SUS at 100 °F[1-5, 18-21]. These products are packaged in plastic, metal, and glass bottles. Fifteen out of the sixteen packages had continuous threaded (CT) finishes (that part of a glass or plastic bottle that will receive the cap) with non-child-resistant continuous threaded (NCRCT) plastic and metal caps. The sixteenth sample was a metal container with a one piece permanently attached flip-top ASTM Type IIIA (snap cap) CR (non senior friendly and non CT finish) plastic cap for metal cans[20]. The characteristics of these packages are summarized in Table 1.

Table 1. Description of Packages for Products Containing 10% Hydrocarbons or More By Weight and Less Than 100 SUS at 100 °F

Cap					Bottle			
Size (mm)	**Type**	**Material**	**Long Skirt (mm)**	**Applicator / Dispenser**	**Size (Oz.)**	**Product**	**Material**	**Tamper Evident Feature**
28	NCRCT	Plastic		flip-top	20	Baby oil	PETE*	none
20	NCRCT	Plastic	18	Flip-top	4	Baby oil	PETE	none
20	NCRCT	Plastic		separate, pipet	1	Bath aroma oil	glass	none
24	NCRCT	Plastic	36	none	8	Bath & Body oil	PETE	none
15	NCRCT	Plastic	42	built-in, brush	0.5	Nail Enamel	glass	none
15	NCRCT	Plastic	41	build-in, brush	0.4	Nail care	glass	none
18	NCRCT	Plastic	26	build-in, brush	1	Cuticle softener	glass	none
24	NCRCT /overcap	Plastic		pump	8	Tanning oil	vinyl	none
24	NCRCT	Plastic	35	flip-top	16	Tanning oil	PETE	none
18	NCRCT	Plastic	24	none	2	Makeup remover	plastic	Yes, Foil
24	NCRCT	Plastic	75, long neck	none	12	Carburetor cleaner	vinyl	none
24	NCRCT	Plastic	75, long neck	none	12	Gas treatment	vinyl	none
18	ASTM Type IIIA(2)	Plastic		flip-top	8	Adhesive remover	metal	none
26	NCRCT	metal		none	16	Sealer finish	metal	none
33	NCRCT	metal		built-in, brush	4	Shoe-water Repellant	glass	none
33	NCRCT	metal		none	4	Spot remover	glass	none

* PETE = polyethylene terephthalate

As Table 1 shows, all of the non-child-resistant (NCR) caps are capped to the corresponding bottles with a continuous threaded (CT) finish. However, some caps have additional product dispensing features that allow the packages to dispense products without separating the caps from the corresponding bottles. Technical feasibility for each dispensing feature type is addressed below:

I. Continuous Threaded (CT) Packages

A continuous threaded package has matching spiral ridges on both the inside of a cap and the outside neck of the corresponding bottle. The package is secured by rotating, screwing, or torquing the cap on the bottle clockwise without a downward pushing force. The package is opened by a counterclockwise torque. The hydrocarbon containing products are packaged with different types of finishes within the family of CT designs. Some examples are: the 400 and 425 Shallow CT series, the 410 and 415 Tall CT series, and the 430 Pour-out series designs. While the 400 and 425 Shallow CT series designs are standard designs, the 410 and 415 Tall CT series designs have long skirt caps. The 430 Pour-out series design bottle is used to minimize spillage of a liquid product when the product is poured out of the bottle. There are ASTM[6] Type I (continuous threaded), 400, 425, 410, 415, and 430 series senior friendly CR packages available on the market, and additional packages with special features (depending on the need(s) of a product manufacturer) can be designed by CR packaging manufacturers to replace the NCRCT packages[8-12].

A. Packages without Applicators or Dispensers as an Integral Part of a Package

Six of the 15 packages had no integrated applicators or dispensers. Also, one package had a separately provided disposable plastic pipet. Since these packages have no applicators, dispensing mechanisms, or the dispensing mechanism was not an integral part of the closure system, technical feasibility for these packages can be met with commercially available 20 mm and higher finish size ASTM Type I senior friendly CR packages[8-12]. Product manufacturers that package their products with less than 20 mm finish size may need to change the finish size to at least 20 mm. Product manufacturers that package their products with very long skirt finish NCRCT packages may need to modify their bottles' skirts to fit existing ASTM Type I senior friendly CR caps. There are ASTM Type I, 410 and 415 series design senior friendly CR packages with up to a 27 mm long skirt on the market[13]. Therefore, it is technically feasible to make or use existing ASTM Type I senior friendly CR packages for products without built-in applicators or dispensers.

B. Packages with Flip-Top Dispensers

Four packages had flip-top dispensers. A flip-top dispenser is an integral part of a cap with a top that flips open to a certain inclined angle to dispense a product through a small opening when the bottle is turned upside-down and squeezed at its opposite sides. At this time, the staff is not aware of a commercially available senior friendly CT finish CR cap with a flip-top dispenser. Products currently packaged in bottles with NCR flip-top dispensers can be packaged in ASTM Type I senior friendly CR packages that have plug-in insert dispensers[10]. A plug-in insert is an

insert that has a small (usually 1 to 2 mm diameter) dispenser at its center and that fits tightly (friction fit) to the inside opening of a bottle. Product packaged in an ASTM Type I senior friendly CR package with a plug-in insert is accessed the same way as product packaged in the NCR flip-top dispenser. One exception is that the ASTM Type I cap is removed before the product is squeezed out from the bottle, but the flip-top is an integral part of the NCRCT cap. The ASTM Type I caps with the plug-in inserts are commercially available on the market to replace CT finish caps with flip-top dispensers. Product manufacturers that package their products with a very long skirt finish NCRCT flip-top packages may need to modify their bottles' skirts to fit existing ASTM Type I senior friendly CR caps, or will need to redesign the CR caps to fit the very long skirt bottles. It is technically feasible to make or use existing ASTM Type I senior friendly CR packages for products with flip-top dispensers.

C. Packages with Built-In Brush Applicators

Four packages had a built-in applicator brush at the inside center of their caps. At present, there is no senior friendly CR package with a built-in applicator brush to replace the smaller (20 mm or less) size finish NCRCT packages with a built-in applicator brush. There is, however, a manufacturer that has a 28 mm ASTM Type I, senior friendly CR package with a built-in insert that can be used to attach an applicator brush[10]. The company also makes a 20 mm ASTM Type I, CR cap without a built-in applicator brush. The same manufacturer indicated that he could produce a 20 mm or higher size ASTM Type I, senior friendly CR package with a built-in applicator brush[31]. Some packages with a built-in applicator brush have less than 20 mm diameter size finishes. There are similar products that are packaged in 20 mm diameter finish packages. Product manufacturers who use this type of packaging may need to use at least a 20 mm diameter finish package to have a senior friendly CR package. Therefore, it is technically feasible to make ASTM Type I senior friendly CR packages with built-in brush applicators for products that require them.

D. Packages with Pump Dispensers

One package had a NCR pump. The pump mechanism is permanently attached to the bottle. Therefore, product is accessed only through the NCR pump itself. At present, there is no senior friendly CR pump on the market. However, one of the following options can be used to package hydrocarbon containing products in senior friendly CR packaging:

1. A manufacturer has a prototype single piece, hinged, flip-top, ASTM Type IIID (snap cap) senior friendly CR overcap that can be permanently attached to a bottle[24]. The overcap is designed to enclose a NCR pump's actuator. At this time, the ASTM Type IIID senior friendly CR overcap has not been produced for marketing. Another manufacturer is currently working on a small diameter size senior friendly CR overcap for lidocaine containing products[16]. This overcap may be used to overcap the NCR pump. A third manufacturer has a prototype ASTM Type VII overcap that may be used to enclose a NCR overcap for smaller size packages[22,30].
2. A mechanical finger press pump manufacturer has indicated that the company can make a senior friendly CR, metered, finger press pump[14,15]. A metered finger press pump is usually used to deliver a specific dose of medical product. In this case, a metered pump probably is not needed for the product tested. Staff believes that if it is technically feasible to make a more

complicated metered senior friendly CR finger press pump, then it is technically feasible to make a less complicated non-metered senior friendly CR finger press pump that could be used for hydrocarbon containing products.
3. Similar products are currently packaged with flip-top dispensers and flip-top dispensers could be used instead of pumps[2,35]. For packages with flip-top dispensers, as in **B.** above, an ASTM Type I senior friendly CR package with a plug-in insert dispenser can be used to comply with the PPPA standards. Therefore, for hydrocarbon containing products packaged with NCR pumps existing ASTM Type I senior friendly CR packages could be used.

Therefore, it is technically feasible to make senior friendly CR finger press pumps or to substitute existing ASTM Type I and III senior friendly CR packages for products that require finger press pumps.

E. Pressurized Aerosol Packages

Aerosol packages that produce a stream flow of hydrocarbon containing products would be included in the PPPA special packaging requirements. When applicable, products that must be in aerosol form and products that require metal containers have to meet the PPPA younger-adult test requirements of 16 CFR 1700.15 (b)(2)(ii). There are ASTM Type VII senior friendly CR overcaps available on the market that may be used with these type of products[22].

F. Packages with a Mechanical Trigger Spray Dispenser

Some hydrocarbon containing products may be packaged with a mechanical trigger spray dispenser (one product manufacturer has an ad for a sunscreen product that may or may not contain hydrocarbons that is packaged with a NCR mechanical trigger spray dispenser). There is a senior friendly CR mechanical trigger spray dispenser (ASTM type IX) on the market that can be used for hydrocarbon containing products to replace the NCR packages with a mechanical trigger spray dispenser[27]. The senior friendly CR mechanical trigger spray dispenser has a NCRCT finish and is attached to a CT finish bottle. To make the package CR, the mechanical trigger spray dispenser either has to be permanently attached to the bottle or it has to have a CR mechanism to prevent access to product by children under five years of age.

II. Packages with Snap Cap Dispensers

One package had a Twist-Flip, Captive Hinge, ASTM Type IIIA (snap cap), CR cap with a spout dispenser on a metal container. This package does not comply with the senior friendly CR packaging requirements. The manufacturer that makes this package has another CR snap (ASTM Type IIIG) flip-top cap that can replace the ASTM Type IIIA package[23, 34]. The ASTM Type IIIG flip-top cap package design complies with the senior friendly CR packaging requirements (Note: This senior friendly CR flip-top is used for a container that does not have a CT finish; therefore, it can not be used with the NCRCT flip-top packages.) Therefore, it is technically feasible to make senior friendly CR snap caps with dispensers.

In addition to the above packages, packages that have thermal seals for single-use products were evaluated. One hydrocarbon containing product was in a package that had a foil thermal seal tamper evident feature. The label on the package indicated that the entire contents should be used at once. Any PPPA regulated single-use product is required to be packaged in a senior friendly CR packaging at the first opening. Neither the thermal seal nor the NCRCT cap used with the thermal seal met this requirement. Packages evaluated by the staff that had a thermal seal were easily opened and would probably not meet the CR requirements for the first opening. The staff has no data demonstrating the foil thermal seals meet the special packaging requirements. Product manufacturers who choose to use thermal seals as a CR mechanism would need to protocol test the package to ensure that it complies with the CR packaging requirements.

The staff concludes that available data support the finding that it is technically feasible to produce special packaging for products containing 10% hydrocarbons or more by weight and a viscosity of less than 100 SUS at 100 °F.

PRACTICABILITY

I. Continuous Threaded (CT) Packages

A. Packages without Applicators or Dispensers as an Integral Part of a Package

Some hydrocarbon containing products are already packaged in ASTM Type I senior friendly CR packages[28]. This demonstrates that the ASTM Type I packages can be adapted to modern mass production and assembly line techniques[8-12]. All of the NCR packages that are used to package hydrocarbon containing products have a CT finish. The ASTM Type I senior friendly CR caps also have a CT finish. Therefore, mass production and assembly line techniques currently used to package the hydrocarbon containing products in NCR packaging without a built-in applicator or dispenser can also be used with minimum adjustments to package the products in the ASTM Type I senior friendly CR packaging.

B. Packages with Flip-Top Dispensers

At present, to the staff's knowledge, there is no commercially available CT finish senior friendly CR package with a flip-top dispenser. However, ASTM Type I packages with a plug-in spout dispenser can be used to replace the NCRCT packages with a flip-top dispenser[9]. ASTM Type I packages with a plug-in spout dispenser are already on the market and are used for PPPA regulated products. Therefore, with some modification, mass production and assembly line techniques currently used to package hydrocarbon containing products in NCRCT packages with flip-top dispensers can also be used to package the same products in the ASTM Type I senior friendly CR packages with a plug-in spout dispenser.

C. Packages with Built-In Brush Applicators

Modern mass production and assembly line techniques used at the product filling line for existing NCRCT caps with built-in applicator brushes may also be used for the CR caps with built-in applicator brushes[31]. At present, ASTM Type I senior friendly CR packages with 20 mm or larger finish exist on the market. A packaging manufacturer indicated that the company could manufacture a 20 mm or larger size finish senior friendly CR package with a built-in brush applicator[31].

D. Packages with Pump Dispensers

Modern mass production and assembly line techniques used at the filling line for existing NCR pumps may also be used for senior friendly CR packages with a pump dispenser. It is also practicable, with some changes, to substitute existing ASTM Type I and III senior friendly CR packages for products that require finger press pumps.

E. Pressurized Aerosol Packages

Modern mass production and assembly line techniques used at the filling line for existing pressurized aerosol packages with NCR overcaps may also be used for pressurized aerosol packages with senior friendly CR overcaps with no or minimum modification.

F. Packages with a Mechanical Trigger Spray Dispenser

Modern mass production and assembly line techniques used for packages with a NCR mechanical trigger spray dispenser can also be used with packages with a senior friendly CR mechanical trigger spray dispenser (ASTM type IX).

II. Packages with Snap Cap Dispensers

ASTM Type III (snap cap) senior friendly CR packages are available on the market that are sold for charcoal lighter products and other products with metal containers[23]. These packages can replace the ASTM Type IIIA non-senior friendly CR packages without any change to the existing assembly line techniques used at the product filling line.

The staff concludes that information is available to support the finding that special packaging for products containing 10% hydrocarbons or more by weight and a viscosity of less than 100 SUS at 100 °F is practicable.

APPROPRIATENESS

I. Continuous Threaded (CT) Packages

A. Packages without Applicators or Dispensers as an Integral Part of a Package

There are already senior friendly CR ASTM Type I, packages on the market appropriate for hydrocarbon containing products[28]. Most of the hydrocarbon containing products are packaged with NCRCT plastic packages. Most of the senior friendly CR, ASTM Type I, packages are

manufactured with similar plastic materials. Although, some plastic materials may not be appropriate for some hydrocarbon containing products (such as solvents), one CR packaging manufacturer has advertised ASTM Type I senior friendly CR packages that are appropriate for solvents and automotive additives[32]. For hydrocarbon containing products that are packaged in NCRCT metal containers with metal caps, there is at least one manufacturer that manufactures a plastic on metal ASTM Type I cap for metal finish cans to replace the NCRCT metal caps[33]. Therefore, there are ASTM Type I packages that can replace the NCRCT packages without built-in dispensers or applicators without interfering with the intended storage or use of the hydrocarbon containing products.

B. Packages with Flip-Top Dispensers

ASTM Type I senior friendly CR packages with a plug-in spout dispenser are manufactured with similar materials as the NCRCT packages with a flip-top dispenser[31,32]. Therefore, ASTM Type I packages with a plug-in spout dispenser would equally protect the integrity of the hydrocarbon containing products as the NCRCT packages with a flip-top dispenser, and would not interfere with the intended storage or use of the hydrocarbon containing products.

C. Packages with Built-In Brush Applicators

The NCRCT packages with a built-in applicator brush are manufactured with thermoset plastics (a thermoset is a polymer that is typically made by a polymerization reaction that is not reversible and is characterized by a structure that has a high degree of cross-linking between polymer chains). One packaging manufacturer that has a 28 mm, ASTM Type I cap with a built-in insert for an applicator brush also manufactures a 20 mm NCRCT cap with a built-in applicator brush for hydrocarbon containing products. Both the ASTM Type I and NCRCT caps are made from identical thermoset materials, and the company can make a 20 mm or larger size ASTM Type I cap with a built-in applicator brush with identical materials to the existing NCR package[31].

D. Packages with Pump Dispensers

There is one prototype senior friendly CR ASTM Type IIID overcap that can be used to overcap the NCR pump actuator. In this case, there would be no direct product contact with the senior friendly CR overcap; therefore, the appropriateness of the raw material(s) with which the senior friendly CR overcap is manufactured is not relevant. Existing ASTM Type I and III senior friendly CR packages that are manufactured with similar materials as the packages with a NCR finger press pump can also adequately protect the integrity of the hydrocarbon containing products and would not interfere with the intended storage or use of the products.

E. Pressurized Aerosol Packages

Pressurized aerosol NCR overcaps would need to be changed to a CR overcap to comply with the PPPA standards. In this case, because there would be no direct product contact with the CR mechanism (CR overcap), the appropriateness of the raw material(s) with which the CR overcap is manufactured is not relevant.

F. Packages with a Mechanical Trigger Spray Dispenser

The ASTM Type IX senior friendly CR mechanical trigger spray dispenser is manufactured with similar plastic materials as the NCR mechanical trigger spray dispensers on the market. This senior friendly CR mechanical trigger spray dispenser could be used for hydrocarbon containing products and can adequately protect the integrity of the products and would not interfere with their intended storage or use.

II. Packages with Snap Cap Dispensers

The ASTM Type IIIG senior friendly CR snap cap is manufactured with similar materials as the ASTM Type IIIA CR snap cap. Therefore, the ASTM Type IIIG senior friendly CR snap cap could be used without changing containers to adequately protect the integrity of the hydrocarbon containing products and would not interfere with their intended storage or use.

The staff concludes that data are available to support the finding that special packaging for products containing 10% hydrocarbons or more by weight and a viscosity of less than 100 SUS at 100 °F is appropriate.

EFFECTIVE DATE

Section 8 of the PPPA specifies that the effective date shall not be sooner than one hundred eighty days or later than one year from the date such regulation is final, unless the Commission finds, for good cause, that an earlier date is in the public interest.

I. Continuous Threaded (CT) Packages

A. ASTM Type I Packages without Dispensers or Applicators

The NCRCT packages without dispensers or applicators can be replaced with currently commercially available ASTM Type I package designs with some adjustments to currently used product filling lines within six months[32]. However, there are packages with a very long skirt that would need bottle changes or redesign of commercially available ASTM Type I caps.

B. ASTM Type I CR Packages with Flip-Top Dispensers

The NCRCT packages with flip-top dispensers can be replaced with ASTM Type I packages with plug-in spout dispensers. The ASTM Type I package designs are also currently available on the market. However, many of this packages have a very long skirt that would need package redesign or bottle changes to adapt existing commercially available senior friendly CR packages.

C. ASTM Type I CR Packages with Built-In Brush Applicators

There is no senior friendly CR package with a built-in applicator brush on the market, and some of the product manufacturers would need to change their bottle sizes to at least 20 mm diameter finish in order to use a senior friendly CR packaging with a built-in applicator brush. This would involve time for tool design to production, protocol testing, and changes at the production line.

D. Packages with Pump Dispensers

The senior friendly CR ASTM Type IIID overcap that can be used to overcap the NCR pump actuator is a prototype overcap. Therefore, this overcap has to be fully developed and mass produced. Some adjustments to the bottles may be needed to permanently attach the overcap to the bottles. Also, product filling lines may have to be modified to accommodate the packaging changes.

E. Pressurized Aerosol Packages

For products that are packaged in standard pressurized aerosol packages, there are senior friendly CR overcaps available on the market. However, the senior friendly CR overcaps are for larger size (209 or 2-9/16" standard size) aerosol cans. Senior friendly CR overcaps for smaller size overcaps would have to be designed for marketing[30].

F. Packages with a Mechanical Trigger Spray Dispenser

Hydrocarbon containing products that may be packaged with NCR mechanical trigger spray dispenser could be replaced with an ASTM Type IX senior friendly CR package that has a mechanical spray dispenser. To make the package CR the mechanical trigger spray dispenser either has to be permanently attached to the bottle or it has to have a CR mechanism.

II. Packages with Snap Cap Dispensers

There are ASTM Type III senior friendly CR packages on the market to replace the ASTM Type IIIA CR (non senior friendly) packages for hydrocarbon containing products.

While there are senior friendly CR packages readily available to replace some of the NCR packages described above, changes from tool design to product filling line would be required to replace many of the NCR hydrocarbon containing packages with ASTM Type I, II, III, VII, and IX, senior friendly CR packages. Therefore, an effective date of one year is recommended.

CONCLUSION

The staff concludes that data support the findings that special packaging for products containing 10% hydrocarbons or more by weight and a viscosity of less than 100 SUS at 100 °F is technically feasible, practicable, and appropriate. Senior friendly CR ASTM Type I caps are available on the market to replace the NCRCT caps. There is a senior friendly CR, snap cap, ASTM Type IIIG, package design that satisfies the PPPA standards to replace the ASTM Type IIIA CR (not senior friendly) snap cap for metal containers. Senior friendly CR overcaps can be developed to overcap the NCR pumps to comply with the PPPA standards. There is at least one prototype senior friendly CR ASTM Type IIID overcap that can be permanently attached to a bottle, and that can enclose a pump's actuator. This prototype package design has been protocol tested and complies with the special packaging standards. Senior friendly CR marker type tube packages can be developed. For hydrocarbon containing products that produce a stream flow,

there are ASTM Type VII senior friendly CR standard (209 size) overcaps on the market, or they can be developed for smaller size overcaps. For hydrocarbon containing products that require mechanical trigger spray dispenser, there is an ASTM Type IX senior friendly CR package on the market. Product assembly line techniques used for the NCR packages can be adapted for the senior friendly CR packages. Some petroleum distillates containing products such as furniture polish and prepackaged kindling and/or illuminating preparation are already required to be packaged in senior friendly CR packaging, indicating that senior friendly CR packaging are available that can adequately protect the integrity of the hydrocarbon products and do not interfere with their intended storage or use.

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TAB F

United States
CONSUMER PRODUCT SAFETY COMMISSION
Washington, D.C. 20207

MEMORANDUM

DATE: April 26, 1999

TO : Suzanne Barone, Ph.D., EH
Project Manager, Petroleum Distillates

Through: Warren J. Prunella, AED, EC

FROM : Marcia P. Robins, EC

SUBJECT: Economic Considerations: Proposal To Require Child-Resistant Packaging For Household Products That Contain Hydrocarbons of Low Viscosity

The Directorate for Economic Analysis reviewed the economic, small business, and environmental effects of the subject proposal. Attached are the findings of these reviews.

Attachment(s)

Economic Considerations: Proposal to Require Child-Resistant Packaging for Household Products That Contain Hydrocarbons of Low Viscosity

The Consumer Product Safety Commission (CPSC) published an advance notice of proposed rulemaking (ANPR) that, if issued as a final rule, would require that certain household products containing hydrocarbons meet child-resistant (CR) or 'special packaging' standards under the Poison Prevention Packaging Act (PPPA).[1] The products covered under the proposal would include all those containing hydrocarbons at 10% or more by weight and having a viscosity less than 100 Saybolt Universal Seconds (SUS) at 100 °F.

CR packaging requirements are already in effect for some specific-use hazardous hydrocarbon-containing household products. These products include prepackaged illuminating fuels, varnishes, non-emulsion furniture polish, and paint solvents. However, other consumer products with the same or similar chemical compositions are not covered under the PPPA, including some that are required to meet labeling requirements under the Federal Hazardous Substances Act (FHSA) administered by CPSC, and some that are regulated under the Food and Drug Administration's Federal Food, Drug and Cosmetic Act (FDCA). The purpose of the proposed CR packaging requirements is to protect children from serious illness or injury from hazardous hydrocarbon-containing products that are not already subject to the PPPA.

The ANPR requested written comments concerning the scope of a rule and regarding products that might be subject to the rule. Specifically, the ANPR sought information on:

1. Chemical properties of individual consumer products (including their form, formulation, and viscosity);
2. User and use patterns;
3. Current packaging and labeling;
4. Economic information (including sales volume, prices, and potential costs and other impacts of CR packaging); and,
5. Poisoning incident information.

[1] *Federal Register*, February 26, 1997.

Overview

Staff sent copies of the ANPR to 9 trade associations (representing over 1300 small and large companies) and to over 200 individual manufacturers of consumer products that may contain hydrocarbons. Additionally, an article about the ANPR and request for information appeared in the journal *Chemical Times & Trends*, July 1997.[2]

Three trade associations provided comments on economic issues: the Arts & Creative Materials Institute (ACMI); the Chemical Specialties Manufacturers Association (CSMA); and, the Cosmetic, Toiletry, and Fragrance Association (CTFA). The comments focused on (1) costs of CR packaging for specific types of packaging or products, and (2) the effects of the proposal on some manufacturers because of the uniqueness of their products. Only a few individual companies provided comments relating to economic issues.

The following report provides information on the products likely to contain hydrocarbons with characteristics subject to the proposal and reviews comments on the ANPR on economic issues. Hydrocarbon-containing products regulated under the FHSA and FDCA are discussed separately.

HYDROCARBON-CONTAINING PRODUCTS REGULATED UNDER THE FEDERAL HAZARDOUS SUBSTANCES ACT

Market Information:

Hydrocarbon-containing products for consumer use regulated under the FHSA appear in many product categories including: adhesives, air fresheners, all purpose cleaners, all purpose lubricants, art materials such as markers, automotive fluids and cleaners, metal cleaners and

[2] Published by the Chemical Specialties Manufacturers Association.

polishes, paint solvents, shoe polishes, spot removers, and water repellents. The products are dispensed in aerosol, gel, liquid and solid form.

Based on a survey of just a 'few' of its 400 member companies, the CSMA reported that an average of about 80 million units of hydrocarbon-containing products are sold annually. The CSMA said its members consider product formulation to be confidential business information. One individual company (membership in CSMA is unknown) reported annual average sales of about 2 million units of hydrocarbon-containing products in bottles and cans. However, no information on product category or formulation was provided.

Table I provides 1996 dollar and unit sales for some categories of *automotive and household cleaning products* that are likely to contain products formulated with hydrocarbons. However, the data do not reveal the share of the market attributable to hydrocarbon-containing products with characteristics that meet the criteria for the proposed rule or that are now packaged CR.

TABLE I

Selected Household Product Categories Likely to Contain Products Formulated with Hydrocarbons

Product Category	$ Sales (million)	Units* (million)	Average Retail Price ($)
Auto treatments/other auto fluids	276.9	164.6	1.68
Auto waxes/polishes	218.5	83.9	2.60
Furniture polish	212.0	54.0	3.93
Floor cleaners/waxes, wax removers	109.7	47.6	2.30
Shoe/vinyl polish/ cleaner/wax	31.0	13.1	2.37
Specialty cleaner/polish	48.4	9.5	5.09
Household lubricants	13.6	7.1	1.92

Source: Share Facts, Find/SVP, 1996

*units are defined by Share Facts as 16 oz equivalents.

The Table 1 data do not include paints, coatings, or art materials. While the National Coating and Paint Association (NCPA), which represents about half of the manufacturers or fillers of aerosol paints, noted that many aerosol paint formulas contain hydrocarbons, the association did not provide unit or dollar sales for these products. However, products packaged in aerosol containers that deliver a fine mist spray would not be subject to the proposed rule. Additionally, non-aerosol paints also are not subject to the proposed rule because of their high viscosity.

The ACMI represents about 200 member companies that manufacture art and creative materials. ACMI surveyed its members and reported less than 60 (exact number unknown) sell products that would be covered under the proposal. The association wrote that the products to which the proposal would apply are fairly specialized products used by adults (product types unspecified) in the art/hobby fields and that the products may not have a large sales volume. No unit or dollar sales were provided.

Packaging Costs

Neither the ACMI nor CSMA provided information on the potential costs of providing CR packaging for their member's products. The ACMI reported that its members did not provide sufficient cost-related information to respond to the request. ACMI wrote that some member manufacturers are voluntarily using CR packaging for certain hazardous products and that since members "tend to support the proposal and have products already in CR packaging, it would not appear to raise major cost obstacles."

While neither ACMI nor CSMA provided information on potential costs, it might be noted that incremental costs for CR packaging typically range from $0.005 to $0.02 per package. For products using a recently developed CR trigger spray, incremental costs will amount to about $0.025 per package

Small Business Effects

The universe of companies that would be affected by the proposed requirement is not known. At least 1,500 large and small companies were notified of the proposal through trade associations and individual mailings. However, the response to the ANPR provided no information indicating that small businesses would be significantly affected by the proposed CR-packaging requirement. Additionally, there are several reasons to believe that the proposed rule would not have a significant impact on affected companies. Some manufacturers of household products containing hydrocarbons with characteristics subject to the proposal are currently providing CR packaging. Manufacturers of household products typically have diverse product lines that include product formulations that would not be included under the proposal. Thus, the number of products that would require CR packaging may represent a small proportion of a firm's production. Finally, the firms would be able to use up existing inventory, since the rule would not apply to products packaged before the effective date..

Only two individual small companies commented on the packaging costs that would be incurred to convert their products to CR packaging. While both indicated there would be an economic burden, neither provided specific cost information. The product of one company is packaged in an aerosol container and delivers a fine mist spray; the product of the other company is packaged in a tube with a restricted-flow moist-fiber applicator tip. Neither of these package types would be covered under the staff- recommended proposed rule; thus, the proposal will have no effect on these companies.

Based on the response to the ANPR, and the wide availability and relatively small incremental costs of CR packaging, there is no evidence that the proposal will have a significant economic effect on a substantial number of small entities supplying products regulated under the FHSA.

HYDROCARBON-CONTAINING PRODUCTS REGULATED UNDER THE FEDERAL FOOD, DRUG & COSMETIC ACT

Market Information

Mineral oil, a hydrocarbon available in a wide range of viscosities, is used in a number of personal care products regulated under the Federal Food, Drug, and Cosmetic Act (FDCA). Products containing mineral oil with a low viscosity, such as some baby oil, bath, massage, and sensual aroma oils, eye makeup removers, and nail care and sun care preparations, would also be covered under the proposed PPPA rule. While many of these products are typically sold separately, others are sold as part of a gift box that includes several items such as fragrant bath oil packaged with a soap and powder. The products may have aerosol, foam, gel, liquid, lotion, and solid formulations, and use a variety of delivery systems.

The Cosmetics, Toiletry, and Fragrance Association (CTFA), which represents about 275 manufacturers of cosmetic products, commented that most cosmetics product categories containing mineral oil are marketed in solid form and thus do not present an aspiration hazard. The Association also noted that only a few of the cosmetics in liquid form would be subject to CR packaging. This is because most exceed the viscosity limit and/or contain less than 10% hydrocarbons.

Many baby oil products are available in cream, lotion, and gel formulations. These products will not be affected by the proposal because of their high viscosity. Similarly, many sun care products also will not be affected by the proposal because of their high viscosity (creams, gels, lotions, solid sticks) or use of non-hydrocarbon formulations.

In response to the ANPR, CTFA sent a survey to over 200 representatives of member companies and received only 15 completed surveys. CTFA reported that some companies returned the survey stating that they used no hydrocarbons,[3] were not currently marketing subject

[3] Among the non-hydrocarbon oils used in cosmetic products as alternatives to mineral oil are: almond, apricot kernel, avocado, lavender, sesame, rosemary, safflower, soybean, and sunflower oils.

products, or products were not for household use. In addition to products containing hydrocarbons, most manufacturers of cosmetics typically have extensive product lines and use various non-hydrocarbon formulations. The association summarized member comments and provided information without identification of brand or company, and only by product category. There was no indication as to whether the responding companies were 'small' or 'large' businesses. Only manufacturers of baby oil provided market share and unit sales data in response to the survey. Based on these data, CPSC staff estimates annual industry sales of baby oil at about 35 million units.

For *all* cosmetic product categories, *Drug Topics* (May 5, 1997) indicated sales amounted to $2.9 billion and 911.5 million units in 1996. No breakout by type of product was given. However, the trade publication *Happi* (March 1996) reported that sun care products, a cosmetics category with some hydrocarbon-containing preparations, had $393.8 million in sales (almost 70 million units) in drug, food, and mass merchandise stores in 1995.[4] However, *Happi* did not provide a breakout of the products that make up the sun care category that includes sunscreens/sunblocks, self-tanners, and after-sun preparations.

Packaging Costs

Packaging for cosmetic products that may contain mineral oil currently includes finger press and pump dispensers, continuous threaded closures, flip tops with restricted orifices, finger spray pumps, and trigger sprays. Some nail care products are packaged with a plug insert restricted-neck fitting to remove excess product from the applicator brush.

According to a leading closure manufacturer, incremental costs for some types of CR packaging that can be used for baby oil, sun care, and other mineral oil-containing cosmetics are about $0.01 per unit (depending upon size, quantity ordered, and color). These package types include a commercially available package with a CR closure and a restricted-neck, and a dispensing cap with a flip top under development. CTFA commented that a marketer of eye

[4] *Happi* (Household and Personal Products Industry).

makeup remover reported the incremental cost for CR packaging for the company's product would amount to 1.5 cents. Additionally, the incremental cost for a recently developed CR trigger spray is about $0.025 per unit.

There is an unknown quantity of nail care products that may be affected by the proposal. Samples of mineral oil-containing cuticle and nail oils examined by EH staff were packaged with 13-20 diameter neck finishes on bottles with built-in applicator brushes. They contain 0.4 to 1.0 oz of product. It may be necessary for some suppliers to change the closure and bottle finish in order to accommodate potentially available CR packaging. According to EH staff, there are at least two U.S.-based packaging manufacturers that could develop CR closures with applicator brushes.[5] No information is available regarding the incremental cost of such packaging.

Manufacturers may also incur one-time start-up costs in addition to the incremental cost of CR packaging. Initial costs vary widely according to the product and to the extent of package redesign. CTFA provided estimates of one-time packaging costs based on the member survey noted earlier. The estimates for CR packaging for baby oil, bath oil, and sunscreen products ranged from $163,000 to $1.5 million and, depending upon manufacturer, included research and development, new bottle molds, new custom-designed caps, and new tooling for product-filling lines. No specific information was provided to support these costs.

One manufacturer, providing comments independent of the CTFA, estimated the start-up costs for CR packaging for baby oil at $122,000 for tooling and changing parts, assuming that only the closure changed and bottle shapes and sizes were not affected. The estimates for tooling and changing parts for CR packaging for a tanning oil, moisture lotion, and bath oil ranged from $6,100 to $85,100.

[5] Memo from T. Asebe, EH, to S. Aiken, EH, August 1998.

Small Business Effects

The concerns of some cosmetics manufacturers center on the need for custom-design packaging, especially for products with small markets, and on the effect of using CR packaging on exports. As noted earlier, CTFA did not provide information regarding the identity of responding companies; thus, staff does not know if these manufacturers are small businesses. The high start-up cost estimates for custom-design CR packaging were discussed above. One unidentified CTFA member commented "packaging aesthetics is an integral element of cosmetics and are a key factor in packaging decisions and ultimately, consumer purchases." Several companies indicated they would be forced to discontinue various products if CR closures were required because product sales would not support the costs to provide the packaging. Data regarding types of product, formulation, sales volume, and projected packaging costs were not provided.

A number of CTFA member companies also expressed concerns regarding exports of CR packaged cosmetics. According to CTFA, packaging requirements for cosmetics would adversely impact global sales because "of a negative consumer perception in foreign countries about the safety of the U.S. product with a CRC [child-resistant closure] versus the foreign competitor's product that is not child resistant." The association also commented that a foreign competitor's packaging cost could be lower than the U.S. product with a CR closure and that consumers would buy the cheaper product in many cases. Comparisons between foreign and domestic costs and data regarding the value of exports that may be impacted by the proposal were not provided. Staff notes that companies that export affected cosmetic products could always run separate packaging lines; one for CR and one for non-CR packages. Staff also notes that companies may have foreign manufacturing facilities, thus negating the need to export finished products.

CTFA reports that one member company manufacturing a massage oil packaged with a continuous threaded closure and a restricted flow opening would drop the product rather than provide CR packaging. According to CTFA, the product, selling at retail for $26 (6.7 oz) has low sales volume that does not make it "worth the investment to refit with special packaging."

No estimate of the magnitude of the "investment" for CR packaging was provided. Additionally, CTFA reported that one manufacturer of nail products said it would discontinue two products if CR packaging were required. A second nail-product manufacturer anticipated that CR packaging would cost several thousand dollars for custom cap retooling and result in a 40% increase (unstated dollar value) in ongoing packaging costs. The size of these businesses is unknown.

The universe of companies that would be affected by the proposed requirement for CR packaging for products regulated under the FDCA is not known. The draft Notice of Proposed Rulemaking (NPR) would request that suppliers, especially small businesses and organizations representing small businesses, provide specific information about their products and the effect the proposed rule would have on them. However, the response to the ANPR did not provide any indication that many small businesses would be affected. The wide availability and relatively small incremental costs of CR packaging relative to the retail price of cosmetic products suggest that few firms should have a significant economic burden.

Based on the economic information available on the proposed rule affecting products regulated under the FDCA, it appears that the proposed rule would not have a significant economic effect on a substantial number of small entities.

Preliminary Environmental Assessment of Proposal to Require Child-Resistant Packaging for Household Products Containing Hydrocarbons of Low Viscosity

Pursuant to the National Environmental Policy Act, and in accordance with the Council on Environmental Quality regulations and CPSC procedures for environmental review, the Commission has preliminarily assessed the possible environmental effects associated with the proposed Poison Prevention Packaging Act (PPPA) packaging requirements for household products that contain hydrocarbons of low viscosity.

The Commission's regulations at 16 CFR Sec. 1021.5 (c) (3) state that the rules requiring special packaging for consumer products normally have little or no potential for affecting the human environment. Preliminary analysis of the impact of this proposed rule indicates that child-resistant (CR) packaging requirements for the production of marketers of low viscosity hydrocarbon-containing products under the proposed rule will have no significant effects on the environment. The manufacture, use, and disposal of CR closures will present the same environmental effects as do non-CR closures.

TAB G

DRAFT Billing Code 6355-01P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR 1700

Household Products Containing Hydrocarbons; Notice of Proposed Rulemaking

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Consumer Product Safety Commission ("CPSC" or "Commission") has reason to believe that child-resistant packaging may be needed to protect children from serious illness or injury from products that contain low-viscosity hydrocarbons. This notice of proposed rulemaking ("NPR") proposes a rule under the Poison Prevention Packaging Act ("PPPA") that would require child-resistant packaging for many products that contain low-viscosity hydrocarbons. The Commission solicits written comments from interested persons.

DATE: The Commission must receive any comments in response to this notice by [insert date that is 75 days after publication].

ADDRESS: Comments should be mailed, preferably in five copies, to the Office of the Secretary, Consumer Product Safety Commission, Washington, D.C. 20207-0001, or delivered to the Office of the Secretary, Consumer Product Safety Commission, Room 502, 4330 East-West Highway, Bethesda, Maryland 20814; telephone (301) 504-0800. Comments also may be filed by telefacsimile to (301) 504-0127 or by email to cpsc-os@cpsc.gov. Comments should be captioned "NPR for Hydrocarbons."

FOR FURTHER INFORMATION CONTACT: Suzanne Barone, Directorate for Epidemiology and Health Sciences, Consumer Product Safety Commission, Washington, DC 20207; telephone (301) 504-0477, ext. 1196.

SUPPLEMENTARY INFORMATION:

A. Background

The Poison Prevention Packaging Act ("PPPA"), 15 U.S.C. 1471-1476, authorizes the U.S. Consumer Product Safety Commission ("CPSC") to require child-resistant packaging of hazardous household substances in appropriate cases.

Direct aspiration into the lung, or aspiration during vomiting, of small amounts of petroleum distillates and other similar hydrocarbon solvents can result in chemical pneumonia, pulmonary damage, and death. Except in specific instances, the current regulations do not require that these solvents be in child-resistant packaging. However, these

chemicals are the primary ingredients in many different consumer products to which children have access.

The viscosity of a hydrocarbon-containing product contributes to its potential toxicity. Viscosity is the measurement of the ability of liquid to flow. Liquids with high viscosities are thick or "syrupy," and liquids with low viscosities are more "watery." Products with low viscosity pose a greater risk of aspiration into the lungs.

Under regulations issued under the Federal Hazardous Substances Act ("FHSA"), the CPSC regulates the labeling of hazardous household substances containing 10 percent or more by weight petroleum distillates because these products may cause injury or illness if ingested. 16 CFR 1500.14. The PPPA regulations also require child-resistant packaging for some household products containing petroleum distillates. 16 CFR 1700.14. Under these PPPA regulations, certain consumer products containing 10 percent or more by weight of petroleum distillates, and having viscosities less than 100 Saybolt Universal Seconds (SUS) at 100°F, are subject to child-resistant packaging standards. These PPPA-regulated products include prepackaged liquid kindling and illuminating preparations (e.g., lighter fluid) (16 CFR 1700.14(a)(7)), prepackaged solvents for paint or other similar surface-coating materials (e.g., paint thinners)(16 CFR 1700.14(a)(15)), and nonemulsion liquid furniture polish (16 CFR 1700.14(a)(2)).

Because hydrocarbons are not now regulated under the PPPA as a chemical class, many hydrocarbon-based consumer products are not required to be in child-resistant packaging. For example, cleaning solvents, automotive chemicals, shoe-care products, and cosmetics may contain large amounts of various hydrocarbons and are not required to be in child-resistant packaging. The existing child-resistant packaging standard requires child-resistant packaging of prepackaged kerosene for use as lamp fuel; however, a gun cleaning solvent that contains over 90 percent kerosene does not have to meet this requirement. Mineral spirits used as a paint solvent require child-resistant packaging, but spot removers containing 75 percent mineral spirits, and water repellents containing 95 percent mineral spirits, do not.

On February 26, 1997, the CPSC issued an advance notice of proposed rulemaking ("ANPR") to request comments and information about whether to require child-resistant packaging of hazardous household products that contain petroleum distillates and other hydrocarbons. 62 FR 8659. In addition to protecting children from serious injury, a rule requiring all hazardous products containing hydrocarbons to be subject to a child-resistant packaging standard would create a more consistent and comprehensive regulatory approach to child-resistant packaging for these products.

In the ANPR, the Commission solicited information on four specific issues: (1) the appropriate viscosity and/or percentage composition to be used as a threshold for requiring products that contain petroleum distillates to be in child-resistant packaging, (2) the inclusion of aerosol products in a requirement for the child-resistant packaging of products containing petroleum distillates or other hydrocarbons, (3) the scope of a rule to extend beyond petroleum distillates to include other hydrocarbons, such as benzene, toluene, xylene, pine oil, and limonene, and (4) the inclusion of restricted flow as an additional requirement for certain products, which would restrict the amount of product dispensed from an opened package during each attempt.

The Commission also solicited information on products that may be affected by such a rule, including chemical properties, users and use patterns, current packaging and labeling, economic information, and incident reports. The Commission extended the comment period until September 1, 1997, at the request of the Chemical Specialty Manufacturers Association ("CSMA") and the Cosmetic, Toiletry, and Fragrance Association ("CTFA"). 62 FR 22897 (April 28, 1997); 62 FR 38948 (July 21, 1997).

Staff also sent copies of the ANPR to 9 trade associations (representing over 1300 small and large

companies) and to over 200 individual manufacturers of household products that may contain hydrocarbons.

B. The Scope of the Proposed Regulation

After reviewing the comments submitted in response to the ANPR, the Commission decided to propose a broad PPPA rule for household products that contain chemicals capable of causing chemical pneumonia and death following aspiration. The remainder of this Section B describes the scope and form of the proposed rule. Additional discussion of the rationale for these decisions is in later sections of this notice.

The proposed rule applies to prepackaged nonemulsion-type liquid household chemical products, including drugs and cosmetics, that contain 10 percent or more hydrocarbons by weight and have a viscosity of less than 100 SUS at 100°F. Hydrocarbons are defined as compounds that consist solely of carbon and hydrogen. For products that contain multiple hydrocarbons, the total percentage of hydrocarbon in the product is calculated by adding the percentage by weight of the individual hydrocarbon components.

The definition of what is a "household substance" that can be regulated under the PPPA includes both a "hazardous substance" as defined in the FHSA and a "food, drug, or cosmetic" as those terms are defined in the Federal Food,

Drug, and Cosmetic Act ("FDCA").[1] The enforcement of the PPPA with respect to hazardous substances relies on the misbranding and prohibited acts sections of the FHSA. The enforcement of child-resistant packaging requirements applicable to foods, drugs, or cosmetics relies on comparable provisions of the FDCA. Therefore, the Commission is issuing two separate rules, one for hazardous substances and one for drugs and cosmetics, to more closely associate a particular rule with the applicable enforcement mechanism. (Foods also are not covered under the proposed rule, because there are no data indicating a need for child-resistant packaging of food products.)

On November 19, 1998, the staff met with interested trade associations to discuss the scope of the potential rule. The emphasis of the meeting was to obtain information on various products or packaging types that should be included or excluded from the rule (Meeting log, December 3, 1998). Several trade associations submitted comments in response to the meeting. After considering these and the

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[1] A third category of products is included in the PPPA's definition of "household substance." This is "a substance intended for use as fuel when stored in a portable container and used in the heating, cooking, or refrigeration system of a house." 15 U.S.C. § 1471(2)(C). These fuels are not subject to the proposed rule because there is no reason to believe there is a need for child-resistant packaging of such products. (The Commission believes that products such as cans of kerosene sold to consumers likely are not "fuel ... used in the heating ... system of a house," even though some kerosene is used in portable heaters that may be used to heat a house. However, the Commission concludes that such products are "hazardous substance[s]" as defined in the FHSA.)